

REMARKS

Claims 41, 52, 55, 56, 65-66, 68, 70, 72 and 74 were pending for examination in this application. Claims 41, 52, 65, and withdrawn claims 42, 50, and 61 are currently amended. No new matter is added.

Amendments

Amendment and cancellation of certain claims are not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claims 41 and 52 have been amended to clarify that the compound is bonded to NO. Support for this amendment may be found throughout the specification as originally filed. Withdrawn claims 42 and 61 were similarly amended. Other amendments to the claims were made to correct typographical errors. No new matter is added.

Claim Rejections Under 35 USC §112 - Second Paragraph

Claims 41, 52, 55, 56, 65-66, 68, 70, 72 and 74 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the current Office Action, the Examiner noted that the recitation “capable of forming a reversible bond or association with NO” in claims 41 and 52 renders the claims indefinite. Claims 41 and 52 are currently amended to remove the quoted recitation and to clarify that the compound is bonded to NO. In light of these amendments, Applicants respectfully assert that one of skill in the art would understand the metes and bounds of the amended claims as limited to compounds that form a bond when contacted with NO.

The Examiner also noted that the recitation of “substantially no oxygen” in claims 70, 72, and 74 renders the claims indefinite. Applicants respectfully traverse this rejection and its supporting remarks.

Applicants note that every composition subjected to the atmosphere will contain at least trace amounts of oxygen. Thus, in the present context, the recitation “substantially no oxygen” should be interpreted to mean that the composition has been purposively depleted or deprived of oxygen to such an extent that is practically and realistically feasible. Additionally, the Federal Circuit has approved of the usage of “substantially” in patent claims:

Expressions such as “substantially” are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention. Such usage may well satisfy the charge to “particularly point out and distinctly claim” the invention, 35 U.S.C. §112, and indeed may be necessary in order to provide the inventor with the benefit of his invention.

Verve v. Crane Cams, 311 F.3d 1116, 1120 (Fed. Cir. 2002).

In the present context, the recitation “substantially no oxygen” accommodates “the minor variations that may be appropriate to secure the invention” as described by the Federal Circuit because the compositions will likely contain trace amounts of oxygen. Thus, Applicants believe that the usage of “substantially” here satisfies the “particularly point out and distinctly claim” requirement of 35 U.S.C. § 112, second paragraph.

In light of the arguments presented above, Applicants respectfully assert that the amended claims are not indefinite. Therefore, Applicants respectfully request that these bases for rejection be withdrawn.

Claim Rejections Under 35 USC §112 - First Paragraph

Claims 41, 52, 65-66, 68, 70, 72 and 74 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement and written description.

Enablement

According to MPEP 2164.08, “[a]ll questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope

of the claim is enabled. . . . All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further, even the case of *In re Fisher*, cited by the Examiner, states that the scope of enablement must only bear a “reasonable correlation” to the scope of the claims. *See, e.g., In re Fisher*, 427 F.2d 833, 839 (CCPA 1970).”

Claims 41 and 52 have been amended to clarify that the compound is bonded to NO and no longer encompass *any* compound capable of forming a reversible bond or association with NO. Applicants assert that this amendment should greatly reduce the list of potential compounds to those that are bonded with NO, are water miscible, and comprise at least one hydroxyl group. Applicants assert that this amendment affects at least the “breadth of claims” and “quantity of experimentation necessary” factors of *In re Wands*. Applicants assert that the amended claims, when coupled with the substantial amount of guidance provided by Table 1 of the specification and the high level of skill in the art, are enabled when assessed under the *Wands* factors..

With respect to predictability, the Examiner noted that “the skilled artisan would view that it is unlikely that one can predict whether all compounds that meet the requirements as claimed could be used to deliver nitric oxide” and that “one skilled in the art would view that it is unlikely that all compounds meeting the limitations of the claim could be used.” The Examiner then gave the example ricin, which is highly toxic and argues that “it is unlikely that one would use ricin as a delivery vehicle for treatment due to its toxicity.” Applicants respectfully assert that the pending claims are directed to “a composition” and not “a method for treatment.” Accordingly, the pending claims relate to “a composition for the delivery of gaseous nitric oxide.” Whether the compound is unsuited for pharmaceutical treatment or not, because of toxicity or for any other reason, is not relevant, because the claims only relate to a compound’s ability to deliver gaseous nitric oxide and not to its suitability for pharmaceutical treatment. While Applicants disagree that the Examiner’s example of ricin is inoperative within the scope of the current claims, MPEP 216408(b) states “[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no

more effort than is normally required in the art.” Even if the present claims were directed to therapeutic use, one of skill would readily know which compounds (such as ricin) would not be operative.

Accordingly, if a person skilled in the art wanted to use the claimed compounds for pharmaceutical treatment, the person would likely refrain from using well-known toxins such as ricin, or would use it in very low, non-hazardous amounts. The skilled artisan would not use the composition of the present invention in any method of treatment without conventional toxicology screening (well before first-in-man clinical trials). This should be regarded to be part of the knowledge and skill in the art.

Based on the arguments presented above, Applicants respectfully assert that the present claims are enabled for the purpose of delivering NO. Therefore, Applicants respectfully request that this basis for rejection be withdrawn.

Written Description

For a claim drawn to a genus, MPEP 2163 describes three alternative ways the written description requirement may be satisfied:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. (emphasis added)

Further, MPEP 2163 states that “[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (“we are of the opinion that the PTO has the initial

burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims”).”

On page 10 of the Office Action dated June 29, 2009, the Examiner provides a discussion and analysis under the Guidelines for Examination of Patent Applications under the 35 USC § 112, first paragraph, “Written Description” Requirement, as published in the Federal Register, Vol. 66, No. 4. Applicants respectively disagree with the Examiner’s reading of the analysis under the third step (“Determine Whether There is Sufficient Written Description . . .”) of those guidelines. With respect to the determination of genus claims, the guidelines state the disclosure requirements as alternatives: “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics” Federal Register, Vol. 66, No. 4, at page 1106, third column (emphasis added). Applicants therefore assert that the alleged absence of drawings or structures (beyond those reduced to practice) should not be a negative consideration for determining written description. Particularly with respect to the Examiner’s citation of *Fujikawa v. Wattansin*, Applicants note that the case pertained to the provision of a “laundry list” of moieties when the claims at issue were directed to only a sub-genus of the listed moieties. The court found that no “blazemarks” were provided to guide the person of skill to the sub-genus of compounds within the list. Unlike *Fujikawa*, the compounds of Table I all fall within the scope of the claim and therefore do not constitute a “laundry list” without blazemarks to the claimed subject matter.

As an initial matter, Applicants note that claims 41 and 52 have been amended to clarify that the compound are bonded with NO and no longer encompass *any* compound capable of forming a reversible bond or association with NO. Applicants respectfully assert that this amendment narrows the scope of the claimed genus and therefore favorable alters the balance of disclosed representative species to the claimed genus.

As stated by the Examiner, the MPEP does not define what constitute a sufficient number of representative species, and cites the *Gosteli* case where disclosure of two compounds of a genus did

not describe the genus. Other courts have reached the opposite conclusion than reached in *Gosteli*, such as the following cases listed in MPEP 2163:

1. *In re Rasmussen*, 650 F.2d 1212, 1214 (CCPA 1981) (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered);
2. *In re Herschler*, 591 F.2d 693, 697 (CCPA 1979) (disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description."); and
3. *In re Smythe*, 480 F.2d 1376, 1383 (CCPA 1973) (the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of "inert fluid" broadly.).

The Examiner does acknowledge that Table 1 discloses exemplary compounds tested and the specification discloses lists of possible compounds described using functional language. Applicants respectfully assert that Table 1 and these lists represent multiple instances of "actual reduction to practice" as well as "other relevant identifying characteristics" (functional characteristics coupled with disclosed correlation between function and structure) which satisfy the written description requirement.

Applicants further note that the guidelines discussed above clearly state that "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Federal Register, Vol. 66, No. 4, at page 1106. Applicants therefore assert that the provided disclosure would be sufficient to convey possession of the claimed invention to the highly skilled persons in the relevant art. Thus,

the disclosure is sufficient to show that Applicants were in possession of the claimed genus of compounds.

For the reasons stated above, Applicants respectfully request that this basis for rejection be withdrawn.

Claim Rejections Under 35 USC §102

Claims 41, 52, 55, 56, 65-66, 68, 70, 72 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Mailhes et al.

To anticipate a claim, the reference must teach every element of the claim. MPEP 2131. Claims 41 and 52 have been amended to clarify that the composition comprises a compound bonded to NO. Applicants note that Mailhes et al. disclose a composition comprising 1,2-propanediol, which is one of the compounds listed in Table 1 of the present application. However, Applicants also note that the amended claims are directed towards compounds bonded to NO, and not a composition comprising the base compound such as 1,2-propanediol. Furthermore, there is no teaching of bonding 1,2-propanediol to NO in Mailhes et al.

Because Mailhes et al. do not expressly or inherently teach every element of the claims, Mailhes et al. is not anticipating prior art. Therefore, Applicants respectfully request that this basis for rejection be withdrawn.


CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 514862003100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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